

remarks presented below it is requested that the Examiner reconsider and withdraw the rejection of claims 1-11 and 13-19.

The Examiner has rejected claims 1-11 and 13-19 under 35 U.S.C. § 103(a) for being obvious over Cooke et al., J. Clin. Invest. Vol. 90, No. 3, pp. 1168-1172 (Sep. 1992) in view of Pitt et al. (J. Am. Coll. Cardiol. Vol. 26, pp. 1133-1139 (1995)). The Examiner kindly provided abstracts of each of these references. For the Examiner's convenience, applicant has provided herewith the corresponding articles in their entirety. A supplemental Information Disclosure Statement (PTO-1449) is also provided herewith so that the Examiner may indicate his consideration of each of the references in their entirety.

The stated basis for the obviousness rejection of claims 1-11 and 13-19 provided in the Office Action is that Cooke teaches "that the administration of L-arginine improves endothelium-dependent vasorelaxation which is associated with the reduction of atherogenesis," and Pitt et al. teaches "that pravastatin reduces the progression of coronary atherosclerosis." In the opinion of the Examiner, it would have been "obvious to one having ordinary skill in the art to combine the administration of arginine and pravastatin in order to combat the deleterious effects or reduce the atherosclerosis." Applicant respectfully disagrees, believing that the Examiner has not satisfied his burden of establishing a *prima facie* case of obviousness.

Neither Cooke nor Pitt provides any motivation to combine L-arginine and pravastatin. Absent such motivation or suggestion, it is improper to combine the references in support of an obviousness rejection under 35 U.S.C. §103. The Federal Circuit, in a recent case, In re Rouffet, reversed an obviousness rejection where, as in this case, the Examiner improperly pieced together elements in the prior art when there was no motivation to do so:

an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries of the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be 'an illogical and inappropriate process by which to determine patentability.' To prevent the use of hindsight based on the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

47 USPQ2d 1453, 1457-1458 (Fed. Cir. 1998) (citations omitted, emphasis added) See also In re Jones, 21 USPQ2d 1941 (Fed. Cir. 1992), (a *prima facie* case of obviousness requires evidence, "other than the PTO's speculation (if it can be called evidence)" that one of ordinary skill in the art would have been motivated to make the suggested combination).

Cooke teaches the prevention of atherogenesis by vasorelaxation. Pitt teaches the treatment of atherosclerosis by lowering cholesterol. There is no suggestion in Cooke that there would be any benefit or advantage gained by combining pravastatin and L-arginine. Nor is there any suggestions or teaching in Pitt that L-arginine would provide any added benefit or advantage to a pravastatin formulation.

The Federal Circuit has consistently held that in order to establish a proper *prima facie* case of obviousness the PTO must show a motivation, apart from the teaching of the invention, to combine the references. Since neither reference suggests or teaches a reason for the combination of either agent with the other, it is respectfully submitted that a *prima facie* case of obviousness has not been established.

In view of the remarks presented above, it is believed that pending claims 1-11 and 13-19 are in condition for allowance and notice to such effect is respectfully requested. Should the Examiner have any questions regarding the above, the Examiner is invited to initiate a telephone conference with the undersigned.

Respectfully submitted,

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By 
Raymond A. Miller
Reg. No. 42,891
REED SMITH SHAW & MCCLAY LLP
435 Sixth Avenue
P.O. Box 488
Pittsburgh, PA 15230
(412) 288-4192
Attorney for Applicant